May 6, 2019

Zacks Small-Cap Research

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Wize Pharma, Inc. (WIZP-OTC)

WIZP: Initiating coverage – a better treatment for dry eye

Our initial value of $2.93/share for WIZP is based on an NPV for LO2A for Sjögren's Syndrome and conjunctivochalasis (CCH) in the US. Our model assumes that WIZP carries all R&D costs through approval (estimated at $22 million) and out-licenses the product to another company that will handle sales and marketing and pay a 20% royalty on sales to WIZP.

Current Price (05/03/19)	$0.65
Valuation	**$2.93**

OUTLOOK

Wize Pharma, Inc. is seeking FDA approval for LO2A, a proprietary formulation of artificial tears for the treatment of Sjögren's and conjunctivochalasis (CCH) in dry eye syndrome. While the competitive landscape is significant, we believe the company will carve out a modest share of the US market based on LO2A's approval for DES, Sjögren's and CCH in four European nations if it receives FDA approval. Risks to our hypothesis center on the Company's ability to obtain financing to complete its clinical trials and FDA approval specifically for CCH and Sjögren's – which will differentiate the product in the US market.

SUMMARY DATA

52-Week High	**$6.10**
52-Week Low	**$0.28**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**111,890**
Shares Outstanding (mil)	**10**
Market Capitalization ($mil)	**$7**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2019 Estimate	**N/A**
P/E using 2020 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**N/A**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2019					0.0 E
2020					0.0 E
2021					0.0 E

Earnings per share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.02 A	-$0.17 A	-$0.10 A	-$0.32 A	-$0.61 A
2019					-$0.43 E
2020					-$0.67 E
2021					-$0.90 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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INVESTMENT SUMMARY

Company Description: We are initiating coverage on Wize Pharma, Inc., a clinical-stage company focused on developing an in-licensed product, for the treatment of dry eye syndrome (DES) and related conditions including Sjögren's syndrome and conjunctivochalasis (CCH). LO2A is approved and marketed by its inventor in several European nations, with over 1.5 million packages sold in 2018. Wize has the rights to develop LO2A for the US, China, Israel and the option to license the rights for additional markets, including those where LO2A is currently sold. On April 29, Wize released full results for its phase II trial of LO2A in patients with moderate-to-severe CCH. The trial met its primary endpoint of diminishing objective parameters of corneal damage with a strong trend towards statistical significance in a key clinical measure. Wize is also conducting a phase IV study of LO2A in patients with Sjögren's Syndrome. The Company intends to submit these studies to the US FDA in order to discuss the clinical approval pathway. We expect progress towards US FDA approval will be the primary catalyst for share price improvement during the next two years.

Valuation: Our initial value for WIZP of $2.93/share is based on an NPV for LO2A for Sjögren's Syndrome and CCH in the US. Our model assumes that WIZP carries all the R&D costs through approval (estimated $18 million) and then out-licenses the product to another company that will handle sales and marketing and pay a 20% royalty on sales to WIZP. We've taken a conservative approach and used peak net debt of $26 million in our valuation to reflect the cost of funding the business until anticipated approval in 2023. Several factors provide upside to our valuation including: pre-approval partnership that provides milestones and/or R&D cost sharing; a faster, or less-costly path to US approval; and the potential for LO2A sales in other geographies (such as China) and development/sales of other products (such as the recently-announced partnership with Cannabics Pharmaceuticals, Inc. (CNBX-OTC) to explore and develop cannabinoid formulations to treat ophthalmic conditions.

Financials: On April 1, 2018, Wize Pharma reported results for 2018. Net loss totaled $3.6 million, compared with $2.7 million in 2017. Our model is based solely on LO2A and the US market. The Company's current burn rate is $150,000-$200,000 per month; however, that rate will increase once Phase III trials commence. We expect the Company will need $22 million of additional funds to get LO2A through the approval process with the highest cash outflow in 2022 based on costs for the Phase III trial and those associated with a commercial launch.

In 2023, we forecast product sales of $65 million, based on a 0.5% share of both the SS and CCH markets in the US. At a 20% royalty rate, these assumptions translate into $13 million to WIZP's top line. Our long-term operating margin is 90% based on royalty revenues and before corporate overhead.

Sensitivities: Wize Pharma has several competitive advantages in its drug candidate, LO2A, notably existing approval overseas, a long history of safety and significant market share in Switzerland (the first approved market). Regarding Wize Pharma and the US market opportunity, there are a number of complexities that may affect the actual outcome and our estimates, most notably financing and partnership risk as well as what we expect will be a highly competitive market for LO2A based on an active development pipeline.

COMPANY DESCRIPTION

Wize Pharma, Inc., is a clinical-stage company focused on the treatment of dry eye syndrome (DES) and related conditions including Sjögren's syndrome and conjunctivochalasis (CCH). In May 2015, the Company adopted its current business strategy by purchasing the rights to market LO2A in the US, China, Israel and the option to license rights for additional markets from its inventor, Resedevco Ltd.

LO2A – proprietary formulation of an established therapy for multiple medical indications

Developed in the 1990s by Dr. Shabtay Dikstein for the treatment of DES and other ophthalmic conditions, LO2A is a sterile, preservative-free, single-dose artificial tear preparation containing 0.015% sodium hyaluronate as the active ingredient.

Sodium hyaluronate (SH) is a salt of hyaluronic acid (HA) and occurs naturally in the body. In the eye, it forms a layer over the surface of the cornea, helping to keep the cornea moist and protected from environmental and/or physical damage. Recent non-clinical studies suggest that HA may work with cell receptors to both protect and heal corneal epithelial cells.

While some eye drops, including artificial tears, contain SH, LO2A's patented formulation has non-Newtonian viscosity, meaning its viscosity characteristics change under certain conditions. In the case of LO2A, blinking temporarily loosens the product's viscosity, releasing moisture across the cornea. LO2A is designed to mimic the physiochemical properties of mucin, a component of natural tear film produced by the lacrimal gland and goblet cells in the eye.

LO2A was studied extensively prior to approval in its current markets including six published phase II studies and one phase III trial. The pivotal phase III trial compared LO2A to Gel-Larmes (an artificial tear preparation) in patients with moderate-to-severe DES. The study showed that LO2A was significantly better at improving patient symptoms (based on patients rating of subjective symptoms and rating tolerance as good or above) and that LO2A was equivalent to Gel-Larmes in improving signs of DES (using well-established clinical measures).

Additional phase II studies were conducted in Hungary assessing safety and efficacy of LO2A in patients with severe CCH and patients with Sjörgen's. The patients with CCH demonstrated significant improvement in their LIPCOF scores (a measure of conjunctival folds) and other measures. As a result, Hungarian health authorities allowed labeling to include treatment of DES in patients with CCH, and the inventor filed additional patents for the use of LO2A for treating CCH in the US, Israel and Japan. In March 2019, Resdevco received approval to include treatment of DES patients with Sjögren's on its label.

Exhibit 1: Resdevco clinical trials for LO2A

Trial title	Phase	Year	Location	Description
Randomized controlled trial of high molecular weight hyaluronic acid (LO2A) in DES	II	1992	Italy	Efficacy of 30-day treatment with LO2A in reducing severity of DES in 100 patients with moderate to severe DES. Trial was to determine optimal dosing. Single-center trial (Hospital San Biagio)
Double-masked, crossover comparison of a new artificial tear preparation containing hyaluronic acid (LO2A) and Lacrisol in DES treatment	II	1992	Italy	Double-blind treatment of 35 patients with moderate to severe DES to compare efficacy of LO2A vs. Lacrisol at reducing severity of DES and other ocular signs and symptoms. 30-day treatment with LO2A alternated with 30-day treatment of Lacrisol. Single-center trial (University of Florence)
Double-masked clinical trial of an unpreserved hyaluronic acid based eye drops (LO2A) in DES	II	1992	Italy	23 patients with moderate/severe DES reated with LO2A in one eye and Lacrisol in the other for 30 days. Single center trial (University of Genoa)
Clinical evaluation of LO2A eye drops versus reference in patients suffering from DES	II	1992	Italy	Compare efficacy of LO2A with eye drops containing 0.5% HPMC in 16 patients with DES. Single-center trial (University of Rome)
Assessment of tolerance to LO2A eye drops	II	1992	Italy	Assess ocular tolerance of 18 patients with moderate-to-severe DES for 20 days LO2A vs 0.5% HPMC. Single-center (Univeristy of Catania)
Effect of a new tear substitute containing glycerol and hyaluronate on keratoconjunctivitis sicca (DES)	II	1998	Israel	Efficacy of LO2A in patients with DES compared wth their current tear substitute. 25 patients with a history of DES > 1 year. Patients treated for either one week (n=15) or two weeks (n=10). Single-center trial (Hadassah University Hospital)
Acceptability and efficacy of LO2A eye drops vs. Gel-larmes in Moderate to severe DES (Clinical trial protocal EC-921-3)	III	1993	France	Pivotal phase III trial to demonstrate superiority of LO2A to Gel-Larmes in improving patient symptoms and to devonstrate equivalence in reducing severity of DES. 100 patients in six sites (Hospital Hotel-Dieu, Paris). Application QID for 12 weeks.
Efficacy of LO2A in patients with severe CCH (label expansion)	II	2013	Hungary	20 patients with grade 2-3 CCH who had failed treatment with other artificial tear preparations applied LO2A QID for 12 weeks in single arm open label study. Based on results, Hungarian officials amended LO2A labeling to include treatment of DES patients suffering from CCH. (Semmelweis University)
Efficacy of LO2A in patients with DES suffering from Sjögren's Syndrome (label expansion)	II	2016	Hungary	21 patients with moderate/severe DES associated with SS. Single-arm, open label study. LO2A applied QID for 12 weeks. Reduction in LIPCOF score, but no improvement in tear production.

Source: Wize Pharma, Inc., Zacks Investment Research

Established European sales – expanding to new territories

Resdevco licenses LO2A to distributors in exchange for royalties. In 2018, over 1.5 million packages of LO2A were sold in four countries: Switzerland, Germany, Hungary and the Netherlands. Wize Pharma signed distribution agreements for Israel and China. The Company is seeking regulatory approval to sell in China and the Ukraine, and began sales (non-material) in Israel in late 2018. Under its licensing agreement, Wize pays a straight royalty ($0.60 per package or up to 10% of net sales).

Exhibit 2: LO2A in existing markets

Territory	Indication	Manufacturer	Distributor	Packages sold
Switzerland	DES	Fareva	Thea Pharmaceuticals Ltd.	1,100,000
Germany	DES	Pharma Stulin	Pharma Stulin	265,000
Netherlands	DES, Sjögren's	Pharma Stulin	Tramedico	158,000
Hungary	DES, CCH, Sjögren's	Pharma Stulin	PannonPharma	8,000

Source: Wize Pharma, Inc. Resdevco, Ltd.

Wize Pharma strategy for LO2A

As noted, Wize has licensed the right to develop and market LO2A in several markets: US, China and Israel. Sales have begun in Israel (at a non-material level), but most of management's focus is on getting FDA approval and obtaining additional financing to conduct trials and get through the approval process.

Wize's first step has been to ensure that clinical trials will meet submission requirements for the US market. Initially, a lack of funding meant the Company wasn't able to ensure that its trials were getting adequate attention from researchers. For example, the Company's single-center phase II trial was discontinued due to lower-than-planned enrollment and indications that the data quality was inadequate. For example, early data showed no correlation in the reaction of both eyes to LO2A, in sharp contrast to both professional literature and other clinical trials. Before terminating the trial, management conferred with its clinical research organization (CRO), which agreed the execution was flawed and that there was no reason to continue the study.

Exhibit 3: Wize Pharma clinical trials for LO2A

Trial title	Phase	Year	Location	Description
Randomized, double-blind, placebo-controlled study of safety and efficacy of LO2A in patients with moderate to severe CCH	II - completed	2016-2018	Israel	62 patients in multi-center trial. 12 weeks treatment tiime. Primary endpoint is change in lissamine green conjunctival staining score at 3 months. Analysis completed on 49 patients. Met primary endpoint; however, secondary endpoint of change in LGCS did not meet point of statistical significance.
Randomized, double-blind, placebo-controlled pilot study to evaaluate safety and efficacy of LO2A in patients with moderate-to-severe CCH	II - terminated	2017	Israel	Single-center trial abandoned for inadequate amount of quality data as there was no correlation in the reaction of both eyes to LO2A in contrast to professional literature and other trials
Randomized, double-blind study of LO2A vs. Systane Ultra HD	IV	Recruiting	Israel	Evaluate safety and efficacy of LO2A for symptomatic improvement of DES in 60 adult patients with SS. Patients randomized in 1:1 ratio in two treatment groups. 12 week study. Primary efficacy endpoint is change from baseline

Source: Wize Pharma, Inc. Clinicaltrials.gov

On April 29, Wize announced full results for its multi-center phase II trial . The trial met its primary endpoint of diminishing objective parameters of corneal damage in CCH patients (p=0.0079). It is important to note that the patient sample was 20% lower than trial design (49 fully-evaluable patients vs. enrollment of 62 patients), reducing the number of observations under the initial protocol of baseline and at three-months. Under the original protocol on the 49 patients CCH showed an average reduction in Lissamine green conjunctival staining (LGCS) clinical score of -3.5 in LO2A patients versus -1.6 in the placebo group at a level that strongly trends towards statistical significant (p=0.0713). However, by adding all post baseline observation points (baseline, one-month and three-months), LGCS improvement on the smaller patient population showed statistical significance (p=0.0079) consistent with the primary endpoint. This additional analysis gives management evidence to support its belief that had the trial been completed as designed (n=62) that the LGCS scores would have met statistical significance. It is important to note that phase II trials are not required to meet statistical significance for the US FDA, so we don't consider these results to be a setback for LO2A.

Separately, the Company expects to complete enrollment in its phase IV trial of DES patients with Sjögren's Syndrome during 4Q19, with results available in 1Q20. The Company intends to submit its studies, along with results from Resdevco's recent trials to the FDA. The Company expects to seek a pre-IND meeting to discuss the pathway for approval by the end of 2019.

Exhibit 4: Anticipated regulatory activity timeline

	2018		2019				2020	
Activity	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Phase II CCH trial								
Top-line results	X							
Full-results				X				
Phase IV Sjörgens trial								
Enrollment			X	X	X	X		
Full-results							X	
Pre-IND meetings with FDA							X	X

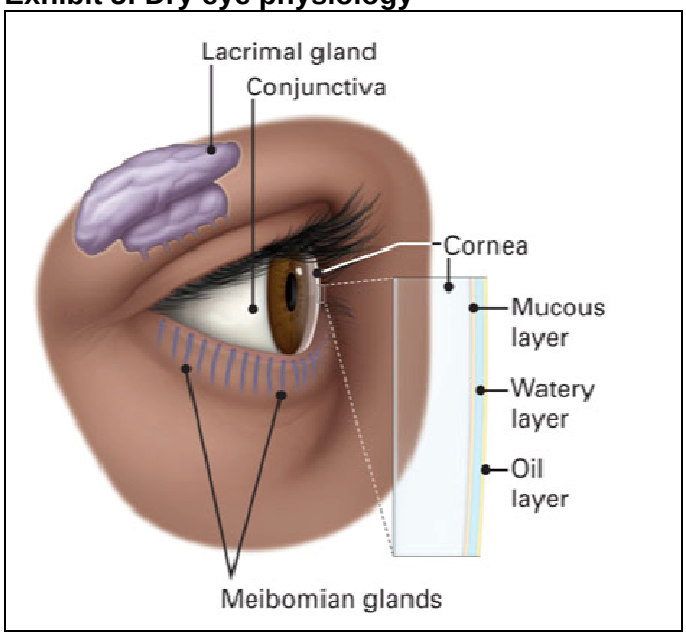
Source: Wize Pharma, Inc., Zacks Investment Research

DRY EYE SYNDROME

Dry Eye Syndrome (DES) describes a cluster of clinically measurable and/or patient-reported symptoms presenting as eye irritation, discomfort or vision problems such as blurring. Patients reporting DES usually exhibit decreased tear production and/or increased tear evaporation. Over an extended period, DES can lead to corneal abrasions or more serious changes to the cornea that may result in permanently deteriorated vision.

Estimates of the prevalence of dry eye vary widely by study and based on the population surveyed, with a range of 7-34% cited. Results from two large epidemiological studies – Women's Health Study and Physician Health Study – place the prevalence at 7% of women and 4% of men over the age of 50 – approximately four million people. However, a 2018 market research study estimates up to 22 million Americans are affected by dry eye at some level of severity (Global Data).

Exhibit 5: Dry eye physiology



Source: American Academy of Ophthalmology

While there are numerous causes of DES, the dysfunctions fall into two broad categories: inadequate tear production (aqueous-based) or rapid tear evaporation/destruction. The majority (60-80%) of DES patients have an evaporative component to their DES.

Inadequate tear production: DES often arises when the lacrimal gland doesn't produce sufficient aqueous (watery) fluid to keep the cornea moist. Clinical signs of inadequate tear production include a reduced tear meniscus, LIPCOFs (lid parallel conjunctival folds) and low Schirmer test results. Medical conditions, such as Sjögren's Syndrome, can negatively affect tear production, as can infection/inflammation, medications, aging and environmental exposure. The lacrimal gland also produces proteins, bacteria and other substances that protect the ocular surface from pathogens while also aiding in corneal cell maintenance and regrowth.

Exhibit 6: Sources of lacrimal gland dysfunction

Pathologic Change	Potential causes
Inflammation/oxidative stress	Sjögren's syndrome
	Autoimmune disorders
	Diabetes
	Thyroid dysfunction
	Aging
Infection	Hepatitis V
	HIV
	CMV
Atrophy	Aging
	Radiation
Environmental	Smoking
	Electronic displays

Source: Conrady et al, Journal of Ophthalmology, 2016

Tear evaporation/destruction: Tear film is a complex structure that has to have the correct balance of characteristics to keep the eye moist and protected, while also being clear enough to see through. Tear film consists of three layers – mucosal, aqueous, and lipid. Meibomian gland dysfunction (MBD) plays a role in the vast majority of evaporative DES cases. Meibomian glands are along the edge of the eyelids where the eyelashes are found. These glands make oil that keeps tears from drying up too quickly. Meibomian secretions can thicken and the glands can become clogged. Thickened secretions don't flow adequately over the eye, allowing the aqueous layer to evaporate prematurely. Clogged glands fail to produce sufficient oil to protect the aqueous layer.

More recently, researchers have focused on the role of goblet cells in tear film inadequacy. Mucin (mucus) is produced by both the lacrimal gland and goblet cells in the conjunctiva (lining) of the upper eyelid and helps tears adhere to the cornea. Researchers found that patients with a low number of goblet cells are most likely to respond to Restasis, the leading prescription treatment for dry eye. Patients with a normal count are less likely to respond to Restasis.

Wize focusing on CCH and Sjögren's syndrome indications for LO2A

Conjunctivochalasis (CCH): CCH is the presence redundant folds of loose conjunctiva (the skin inside the eyelid). Aging is likely the key cause of CCH, although MGD, blepharitis, aqueous DES and previous eye surgeries may also contribute. In CCH, the seal between the conjunctiva and sclera (white part of the eye) loosens, and the resulting conjunctival folds rub against the eye and disrupt the tear film.

The primary clinical measure of CCH is LIPCOF (Lid Parallel Conjunctival Folds), a measure of the number and severity of the lid-parallel conjunctival folds. The LIPCOF scale ranges from grade 0 (absence of conjunctival folds) to grade 3 (multiple conjunctival folds extending beyond the tear

meniscus). Low-grade CCH is managed with eye drops, while high-grade CCH may require surgical intervention.

There are few studies looking at the prevalence of CCH, and as with DES, estimates vary widely. One paper cites epidemiological Chinese population studies suggesting CCH prevalence anywhere from 13-45% in people over age 50. Our model uses an estimate of 1.5% of the US population, or 4-5% of Americans over age 50.

Sjögren's syndrome: Sjögren's syndrome is a chronic, inflammatory, autoimmune disease affecting moisture-producing glands in the body. Sjögren's may primary or it can be secondary to other autoimmune diseases such as lupus and rheumatoid arthritis. Symptoms range from relatively mild (dry eye and dry mouth) to more severe symptoms affecting the whole body. Mild symptoms are managed with artificial tears, punctal plugs, anti-inflammatories and drugs that increase salivary production.

Estimations of primary Sjögren's prevalence vary widely, from 2.2 to 11 of 10,000 people in the US. Diagnosis guidelines from American–European Consensus Group or American College of Rheumatology include specialized tests, including salivary gland biopsy. The higher estimate is based on primary clinical practice observations, which rarely include the specialized testing. The Sjögren's Syndrome Foundation estimates a much higher prevalence of up to 4 million cases in the US. Our model uses an estimate of 0.5% of the population, or 175,000-200,000 cases.

Exhibit 7: Current dry eye treatments in the US (selected)

Class	Product (Maker)	Mechanism of action	Comment
Anti-inflammatory			
	Restasis (Allergan)	Cyclosporine A	Top-selling product for DES indication. Effective primarily for patients with low goblet cell count.
	Cequa (Sun Pharma)	Cyclosporine A	FDA approval and launch in late 2018. Uses nano-micellar technology to deliver higher concentration of cyclosporine into eye.
	Xiidra(Shire)	LFA-1 Agonist	Faster onset of relief than Restatis in clinical trials - 6 weeks vs. 3-6 months.
	Dextenza (Ocular Therapeutix)	Corticosteroid punctal plug	Approved December 2018. Launch scheduled mid 2019.
Devices			
	Lipiflow (Johnson & Johnson)	Heat, pulsation	For MBD. Treatment done in physician's office.
	True Tear (Allergan)	Neurostimulation through nasal passages	For MBD. Launched April 2019. Patient
	NuLids (NuSight Medical)	Physical stimulation of melbomian glands	For MBD. Daily treatment. Patient administered.
	iLux (Tearfilm Innovations)	Heat, compression	For MBD. Physician administered.

Source: EvaluatePharma, Zack Investment Research. Note: Excludes artificial tears and general corticosteroids.

In the US, artificial tears followed by anti-inflammatories (including corticosteroids) are front-line treatment for DES. While both are effective for most patients, they treat symptoms and not the cause of DES. In addition, artificial tears tend to relieve symptoms for a few hours at most and corticosteroids are not designed for long-term use. Restasis, Xiidra, and more recently Cequa, are topical anti-inflammatories that can be used long-term. The downside is expense – often $600/month – the products only treat symptoms and do not appear to treat the underlying causes of DES and they do not appear to work for a large proportion of patients. Several devices are approved for meibomian gland dysfunction (MBD), but three of those require a visit to the physician's office.

The US pipeline for DES continues to lean towards anti-inflammatories/receptor inhibitors, and includes antioxidants and therapies focused on improving the tear film structure. It is important to note that a number of well-established pharmaceuticals are in the early stages of clinical testing as potential treatments for DES (and particularly Sjögren's); however, we don't believe that any of these agents will be approved in the next several years.

Exhibit 8: US pipeline treatments for DES (selected)

Class	Product (Maker)	Mechanism of action	Comment
Anti-inflammatory			
	OCU-310 (Ocugen)	Alpha2-adrenergic receptor agonist	Approved for glaucoma. Phase III trials for DES.
	AXR-159 (Axerovision)	Steroid	First in class differentiated steroid. Phase II
	INVELTYS/KP-121	Steroid	NDA submitted
Immunology			
	TOP-1630 (Topivert)	Protein kinase inhibitor	Phase II/III
	Orencia (Bristol Myers)	T-cell receptor inhibitor	Phase II Sjögren's
	Voclosporin (Aurina)	T-cell receptor inhibitor	Phase II
	AMG/MEDI5872 (Amgen)	Anti-ICOSL	Phase II Sjögren's
	CFZ-533 (Novartis)	CD4 blocker	pre-phase II Sjögren's
	VAY-736 (Novartis)	Anti-BAFF-R	Phase II Sjögren's complete
Anti-oxidant			
	Visomitin/SKQ1 (Mitotech)	Protects against free-radicals	Phase III in US. Approved in Russia
	ADX-102 (Aldeyra)	Reactive aldehyde species inhibitor	Phase III enrolling
Other			
	Lacripep (Tear Solutions)	Synthetic lacritin protein	Phase II. Being tested for Sjögren's
	RGN-259 (RegeneRx)	Therapeutic peptide Thymosin beta 4	Phase III Asia for DES - Plan to submit to FDA

Source: Evaluate Pharma, Zacks Investment Research, Clinicaltrials.gov.

SENSITIVITIES

Wize Pharma has several competitive advantages in its drug candidate, LO2A, notably existing approval overseas, a long history of safety and significant market share in Switzerland (the first approved market). As pertains to Wize Pharma and the US market opportunity, there are a number of complexities that may affect the actual outcome and our estimates.

Financing and partnership risk: We estimate Wize will need project funding of $22 million (including corporate overhead costs) to achieve FDA approval and commercial launch in 2023 based on a single phase III trial. To date, the Company has raised funds through private placements (usually convertible debt and options/warrants). We estimate the Company could raise more than half of its funding needs if existing holders exercised their rights; however, whether or not that happens is largely dependent on share price. For the purposes of this report, we have modeled funding as $22 million in straight debt at 6% with PIK interest until sometime after the commercial launch and we anticipate Wize will hand over sales and marketing to a partner the US (and other geographies) in exchange for royalties (that we have modeled at 20% of sales). However, as the Company is looking at all options, we could see partnership earlier on in the development cycle, perhaps with cost-sharing and milestone payments which would affect our valuation model.

Development risk: While LO2A has been approved to treat dry eye and Sjögren's syndrome (SS) in several established markets, the Company has not applied for US marketing approval. Management intends to meet with the US FDA on next steps late in 2019. For us, the key is getting labeling indication for Sjögren's and CCH, where existing products, such as Restasis, are used off-label. The big win would be if clinical test show that LO2A helps to treat the damage caused by SS and CCH, existing products primarily treat symptoms and prevent further damage. It is important to note, however, that the FDA has been slow to approve treatments for DES. Although products that use HA as the active ingredient are popular outside the US, only one product (Blink Tears) an OTC product that has HA as an inactive ingredient, has been approved. Despite positive Ph III results, the FDA rejected Lantibio's Rejena, an HA preparation in 2009 because it did not show sufficiently positive efficacy vs.placebo.

Competition: The opportunity to treat dry eye is significant with many suffers relying on products that treat the symptoms, such as artificial tears and Restasis, but do little to manage the underlying cause. As noted above, along existing solutions, there are several dozen potential treatments for dry eye in the development pipeline, including many that are already in Phase III testing. Some of these potential treatments are seeking approval for SS and CCH as well, placing them in potential competition with LO2A. Our valuation model is based on a 2023 launch for LO2A in the US and a 5% market share in both SS and CCH by 2031. Earlier approval, additional geographic markets (Wize has the right to sell in China and may purchase the right to sell in other markets), or higher market share represent upside to our valuation model.

Dilution risk: Wize Pharma has relied primarily on a combination of convertible debt, warrants and options to fund its growth, with all investments made by affiliates until October 2018. While management and insiders have not converted or sold their sizeable holdings, investors need to consider the possibility of dilution risk at some point in the future. However, with the announcement of the LO2A phase II results on April 29, the 4.45 million Series B warrants are likely to go unexercised when they expire on or about May 19, 2019 (20 days after phase II results are released), unless the Company's share price rises to over $1.00. The expiration of these warrants reduced dilution potential by 33%.

Exhibit 9: Potential dilution

Derivative	Dilutive shares	Exercise price range	Potential Proceeds ($US 000)
Options	259,896	$3.59-$216.00	1,749
PIPE 2017, 2018 Series A and B	9,659,871	$1.00-$1.97	10,844
PE placement agent and advisor warrants	356,000	$1.00-$1.10	365
Convertible notes (2016/2017)	1,403,949	$0.98-$1.11	1,478
Fufure investment right (2016/2017 loans)	890,138	$1.31-$1.33	1,176
Preferred Series A	850,000		

Source: Wize Pharma, Inc.

VALUATION

Our initial value for WIZP of $2.93/share is based on an NPV for LO2A for Sjögren's Syndrome and CCH in the US. Our model assumes that WIZP carries all the R&D costs through approval (estimated $18 million) and then out-licenses the product to another company that will handle sales and marketing and pay a 20% royalty on sales to WIZP.

We assume a 2023 launch with a wholesale price of $200 for a 30-day supply, or $2,400 per year per patient. Our model builds to peak wholesale sales of c. $550 million by 2031 ($113 million in royalties to WIZP) and 90% operating margins at WIZP before corporate overhead. Our model uses a 15% discount rate on LO2A assumptions, adjusted a 50% for clinical risk. Corporate overhead is discounted at 10%.

We've taken a conservative approach and used peak net debt of $26 million in our valuation because of the Company's need for funding.

Several factors provide upside to our valuation including: pre-approval partnership that provides milestones and/or R&D cost sharing; a faster, or less-costly path to US approval; and the potential for LO2A sales in other geographies (such as China) and development/sales of other products (such as the recently-announced partnership with Cannabics.

Exhibit 10: Valuation model

Valuation by NPV sum-of-the-parts						
Product	**Indication**	**Launch**	**NPV ($mil)**	**Probability**	**rNPV ($mil)**	**rNPV/Share ($)**
LO2A	Sjögrens/CCH	2023	167	***50%***	84	8.17
Corporate overhead			(28)	***100%***	(28)	(2.70)
Net Cash			(26)	***100%***	(26)	(2.54)
Valuation			**113**		**30**	**2.93**

Source: Zacks Investment Research, Company filings.

FINANCIALS

On April 1, 2019, Wize Pharma reported results for 2018. Net loss totaled $3.6 million, compared with $2.7 million in 2017. The increased loss stemmed primarily from increases in research and development expenses associated with its Phase 2 studies of LO2A, along with higher financing and staffing costs.

Profit and loss statement

Our model is based solely on LO2A and the US market. However, investors should note Wize has existing rights to market LO2A in other countries (notably China), the opportunity to purchase marketing rights for other countries and an early partnership with Cannabics to explore development of cannaboid-derived ophthalmic treatments. In 2023, we forecast wholesale product sales of c. $65 million, based on a 0.5% share of both the SS and CCH markets in the US. At a 20% royalty rate, these assumptions translate into $13 million to WIZP's top line. For 2024, we forecast product sales of $123 million and royalties of $25 million. We've modeled peak product sales at wholesale of $550-600 million and royalties of $113 million by the mid 2030s based on a 5% market share in the US for SS and CCH.

Our assumptions are modeled on a straightforward royalty agreement, where the licensee pays Wize 20% of sales, purchases product from the manufacturer and is responsible for all sales and marketing costs. Under this scenario, product costs for Wize consist of royalties paid to Resdevco (up to 10% of sales or $0.60 per package – whichever is higher). These assumptions give WIZP an estimated product margin of 90% before corporate overhead on its royalty revenues. Our model includes $18 million in R&D (including pre-launch royalties to Resdevco), through 2023. After its launch, the royalties to Resdevco will become COGS. We model corporate overhead of $3.1 million in 2019 (of which approximately half is cash expense), growing at 5% pa until 2026 before slowing to 2% long-term.

Cash flow

We expect Wize to be a net user of cash until LO2A is approved and launched. The Company's current burn rate is $150,000-$200,000 per month; however, that rate will increase once Phase III trials commence. We expect the highest cash outflow in 2022 based on costs for the Phase III trial and costs associated with a commercial launch.

Balance sheet

At December 31, 2018, Wize had $3.2 million in cash and $2.7 million of debt on its balance sheet (excluding a current payable of $250,000 towards its annual minimum commitment under its licensing agreement with Resdevco). Our forecast includes $22 million in fundraising during the next four years, with a minimum of $3 million in the current fiscal year. Additional funds may be needed depending on spending needs and whether the Company needs to refinance any of its outstanding debt.

Exhibit 11: Financial summary

INCOME STATEMENT								
Fiscal year	2016A	2017A	2018A	2019E	2020E	2021E	2022E	2023E
Revenue	0	0	0	0	0	0	0	12,913
Cost of sales including payaways	0	0	0	0	0	0	0	(1,291)
Gross Profit	0	0	0	0	0	0	0	11,621
Research & development	(240)	(450)	(694)	(1,050)	(3,150)	(5,000)	(10,000)	(3,000)
Selling, general & administrative	(794)	(1,031)	(2,936)	(3,083)	(3,237)	(3,399)	(3,569)	(3,747)
Operating profit (EBIT)	(1,034)	(1,481)	(3,630)	(4,133)	(6,387)	(8,399)	(13,569)	4,874
Interest income	76	0	2,149	0	0	0	0	0
Interest expense	(181)	(1,485)	(1,798)	(285)	(480)	(807)	(1,513)	(1,602)
Other expense	0	(50)	(365)	0	0	0	0	0
Pretax profit	(1,139)	(2,966)	(3,279)	(4,418)	(6,867)	(9,206)	(15,082)	3,273
Taxes	0	0	0	0	0	0	0	0
Net income (common shareholders)	(1,139)	(2,969)	(3,571)	(4,418)	(6,867)	(9,206)	(15,082)	3,273
Basic shares outstanding	3,023	3,439	5,649	10,230	10,230	10,230	10,230	10,230
Diluted shares outstanding	3,023	3,439	5,649	10,230	10,230	10,230	10,230	10,230
Basic EPS	**($0.38)**	**($0.86)**	**($0.61)**	**($0.43)**	**($0.67)**	**($0.90)**	**($1.47)**	**$0.32**
Diluted EPS	**($0.38)**	**($0.86)**	**($0.61)**	**($0.43)**	**($0.67)**	**($0.90)**	**($1.47)**	**$0.32**
Growth rates & margins								
Revenue growth	NA	NA	NA	NA	NA	NA	NA	NA
Gross profit as % of sales	NA	NA	NA	NA	NA	NA	NA	90%
R&D margin	NA	NA	NA	NA	NA	NA	NA	23%
SG&A margin	NA	NA	NA	NA	NA	NA	NA	29%
Tax rate	NA	NA	NA	0%	0%	0%	0%	0%
EBITDA reconciliation								
Depreciation & amortization	0	1	2	4	4	4	5	5
Stock based compensation	65	19	1,343	1,446	1,916	2,100	2,714	2,699
EBITDA	(969)	(1,461)	(2,285)	(2,682)	(4,467)	(6,295)	(10,850)	7,578

BALANCE SHEET							
Fiscal year	2017A	2018A	2019E	2020E	2021E	2022E	2023E
Cash & equivalents	550	3,215	3,542	2,087	804	967	2,225
Total current assets	**590**	**3,395**	**3,722**	**2,267**	**984**	**1,147**	**4,988**
Property plant and equipment	5	8	9	10	10	11	11
Total Assets	**595**	**3,403**	**3,732**	**2,277**	**995**	**1,157**	**4,999**
Accounts payable	43	34	36	37	39	41	0
Accrued liabilities	446	522	536	550	565	581	(3,110)
Total current liabilities	**489**	**556**	**571**	**587**	**604**	**622**	**(3,110)**
Long-term debt	3,204	2,635	5,920	9,400	15,207	27,721	29,322
Total liabilities	**3,693**	**3,191**	**6,491**	**9,988**	**15,812**	**28,343**	**26,213**
Common stock / additional paid in capital	23,401	30,282	31,728	33,645	35,744	38,458	41,157
Treasury stock	0	0	0	0	0	0	0
Retained earnings / accumulated deficit	(26,452)	(29,997)	(34,415)	(41,283)	(50,488)	(65,570)	(62,298)
Other comprehensive income / (loss)	(47)	(73)	(73)	(73)	(73)	(73)	(73)
Total equity	**(3,098)**	**212**	**(2,760)**	**(7,711)**	**(14,817)**	**(27,185)**	**(21,214)**
Total liabilities and equity	**595**	**3,403**	**3,732**	**2,277**	**995**	**1,157**	**4,999**

CASH FLOW STATEMENT							
Fiscal year	2017A	2018A	2019E	2020E	2021E	2022E	2023E
Cash from operating activities		**(2,208)**	**(2,668)**	**(4,451)**	**(6,278)**	**(10,833)**	**1,264**
Capital expenditures		(5)	(5)	(5)	(5)	(5)	(5)
Proceeds from sale of marketable sec.		258	0	0	0	0	0
Cash from investing activities		**253**	**(5)**	**(5)**	**(5)**	**(5)**	**(5)**
Cash from financing activities		**4,910**	**3,000**	**3,000**	**5,000**	**11,000**	**0**
Net change in cash during period		**2,956**	**327**	**(1,456)**	**(1,283)**	**162**	**1,259**

Source: Company filings, Zacks Investment Research estimates.

KEY LEADERSHIP

Mark Sieczkarek joined as Chairman of the Board in April 2019. Mr. Sieczkarek brings more than 39 years of leadership experience in the medical industry, including from 2006 to 2014 as CEO and Chairman of the Board of Solta Medical (acquired by Valeant Pharmaceuticals) and from 2003 to 2011 as President and CEO of Conceptus, (acquired by Bayer Pharmaceuticals). From 1995 to 2003, Mr. Sieczkarek held multiple roles of increasing responsibility at Bausch & Lomb ("B&L"), ultimately becoming Senior Vice President and President of the Americas region, where he was responsible for the commercial operation of all B&L businesses in the United States, Canada, and Latin America. He also served as President of the European region. Mr. Sieczkarek also held senior executive level positions with KOS Pharmaceuticals, several Bristol Myers-Squibb subsidiaries, and Sanofi Diagnostics Pasteur. Mr. Sieczkarek earned an MBA in Finance from Canisius College in Buffalo, New York and a BS in Accounting from the State University of New York at Buffalo. He also was past Chairman and CEO of NovaBay Pharma and continues to serve there as a Director.

Noam Danenberg was appointed Chief Executive Officer in April 2019 and serves as a director. He was Chairman of the Board from November 2018 to April 2019. He served as Chief Operating Officer from November 2017 until November 2018. Mr. Danenberg has been a strategic advisor of Wize Israel since April 2015. Mr. Danenberg co-founded Panmed Inc., a biomed investment company in 2014. Since 2000, Mr. Danenberg has provided investment consulting services to numerous private and public companies through his wholly owned company, N. Danenberg Holding (2000) Ltd. From May 2014 to January 2015, Mr. Danenberg served as a director of Go.D.M. Investments Ltd. (TASE: GODM). From 2000 to 2012, Mr. Danenberg served as an investment advisor at International Software Consulting Limited and from 2004 to 2008 he served as the Chairman and CEO of Fitracks Inc. From 2006 to 2012, he also served as the Chairman of the Board of Hawk Medical Technologies Ltd. Mr. Danenberg holds a B.B.A. in Computer Science from the European University in Antwerp, Belgium and an M.B.A. from the Boston University Brussels Graduate Center.

Or Eisenberg has served as Acting Chief Executive Officer, Chief Financial Officer, Treasurer and Secretary since the closing of the Merger in November 2017. Mr. Eisenberg has served as the Chief Financial Officer and Acting Chief Executive Officer of Wize Israel since March 2015. From October 2010 to December 2014, he served as the controller of the Katzir Fund Group. From March 2013 to December 2014, he served as either an external controller or Chief Financial Officer of a number of public companies whose shares are listed for trading on the TASE. From October 2007 to October 2010, Mr. Eisenberg was an accountant at Kost Forer Gabbay & Kasierer, a registered public accounting firm, a member firm of Ernst & Young Global. Mr. Eisenberg holds a B.A. from Haifa University in Economics and Accounting and is a Certified Public Accountant in Israel.

Dr. Adam Foley-Comer serves as the Medical Director for Wize Pharma, Inc. Dr. Foley-Comer focuses on development, regulatory strategy, and clinical trial planning and conduct, where he has extensive experience with leading international pharmaceutical companies. Dr Foley-Comer graduated in Medicine from Manchester University is a Fellow of the Royal College of Surgeons and earned his MSc from University College, London.

Michael Belkin, MA, MD has served on the board since July 2013. Dr. Belkin was formerly a professor and now Professor Emeritus, of Ophthalmology at Tel Aviv University in Tel Aviv, Israel, and the Director of the Ophthalmic Technologies Laboratory at the University's Eye Research Institute. Dr. Belkin also serves as a Senior Consultant to the Eye Research Institute at the Singapore National Eye Institute. He was awarded a master's degree in natural sciences by Cambridge University, England, and received a doctorate in medicine from the Hebrew University of Jerusalem. Dr. Belkin previously served as Director of Research, Development and Non-Conventional Warfare Medicine in the Israel Defense Forces Medical Corps. He also established and was the first full-time Director of the Tel Aviv University Eye Research Institute, Chairman of the Tel-Aviv University Department of Ophthalmology and the President

of the Israel Society of Eye and Vision Research, which he co-founded. Dr. Belkin is an author of over 250 scientific publications and more than 25 patents. He is an internationally recognized eye researcher and has received various research awards. His laboratory is dedicated to enabling the transfer of technologies from university-level research to clinical practice by providing expertise and facilities for laboratory, preclinical and clinical studies. He is an entrepreneur and advisor of several ophthalmic companies in the fields of lasers, optics, ophthalmic devices, pharmaceutics and biotechnology. One of his inventions, the ExPRESS miniature glaucoma shunt, is currently used worldwide. He serves as chairman and member of various international and local scientific and professional committees as well as scientific journals' editorial boards.

Yossi Keret has served on the board since the closing of the Merger on November 15, 2017. Mr. Keret served as the Chief Executive Officer, Managing Director and Director of Weebit-Nano Ltd. (ASX:WBT) from August 2015 to October 2017. From October 1996 to October 2015, Mr. Keret served as the Chief Financial Officer of numerous public and private companies, including Eric Cohen Books Ltd. & Burlington English Ltd., Daimler Financial Services Israel Ltd., Pluristem Life Systems Inc. (NASDAQ:PST), M.L.L. Software and Computers Industries Ltd. (TASE:MLL), Internet-Zahav Group, Ltd. (NASDAQ:IGLD) and Top Image Systems Ltd. (NASDAQ:TISA). Mr. Keret commenced his career at Kost Forer Gabbay & Kasierer, registered public accounting firm, a member firm of Ernst & Young Global. Mr. Keret holds a B.A. from Haifa University in Economics and Accounting and is a Certified Public Accountant in Israel. Mr. Keret's qualifications to serve on our Board of Directors include his expertise in financial matters and his serving as the Chief Financial Officer in numerous private and public companies**.**

Dr. Franck Amouyal. Dr. Amouyal joined the board in 2017. He is a medical and surgical ophthalmologist in Israel at Neve Tsedek Medical Center since October 2016 and Koupat Holim Clalit and Meuhedet since November 2016. He conducted his residency and fellowship at the Nord Hospital and La Timone Hospital in Marseille, France, at the Lariboisière Hospital, Paris, France and as a research assistant at the Jules Stein Eye Institute, University of California Los Angeles. Dr. Amouyal is the author of over 10 scientific publications and is a member of the French Society of Ophthalmology (SFO) and the Association for Research in Vision and Ophthalmology (ARVO). He lectures on ophthalmology to optometrists, nurses and medical students. Dr. Amouyal holds a First Cycle and a Second Cycle of Medical Studies degree from the Medical University of Purpan, Toulouse, France.

Joseph Zarzewsky joined the board in 2017. Mr. Zarzewsky has served as the Vice President of Business Development at the Mitrelli Group ("Mitrelli") since June 2010. He has served as the Chairman of "SMAD", a joint venture between Mitrelli and the Harbin Government, China, since June 2011. Mr. Zarzewsky has also served as the Chairman of the Investment Committee of the Harbin Israel Fund since 2012. He has previously served as the Vice President of marketing at Clal Insurance Enterprises Holdings Ltd. (TASE: CLIS) and as the Vice President of Marketing for the Israel Postal Authority. Mr. Zarzewsky has served as a director of Excellence Underwriter House Ltd. since 2007. In 2008, he was appointed as the Honorary Economic Advisor of the Harbin Government, China. In addition, in June 2012, he was honored as an Honorary Citizen of Harbin, China. Mr. Zarzewsky holds an MA in Commercial Law from the University of Tel Aviv and University of California, Berkeley.

Penny Asbell, MD a key opinion leader in the treatment of dry eye syndrome joined Wize Pharma's Scientific Advisory Board in July 2018. As a principal investigator in countless clinical studies sponsored by the National Institute of Health's National Eye Institute and by industry sponsors, Dr. Asbell has participated in the development of pharmaceuticals that have included pivotal treatments for ocular conditions including dry eyes. In June 2018, Dr. Asbell was named to her current position as the Barrett G. Haik Endowed Chair for Ophthalmology in the College of Medicine and Director of the Hamilton Eye Institute at the University of Tennessee Health Science Center (UTHSC). Dr. Asbell joined UTHSC from the Icahn School of Medicine at Mount Sinai (ISMMS) in New York, where she is a professor of Ophthalmology and director of the Cornea Service and of the Cornea Clinical and Research Fellowships. She is vice chair of the ISMMS Appointment and Promotion Committee, medical director of the Faculty Practice for Ophthalmology, and system vice chair for Academic Affairs for the Department of

Ophthalmology. She established Mount Sinai's Lowenstein Foundation Sjögren's Center to provide multi-specialty care for patients with dry eyes and associated systemic problems and founded the Ocular Inflammatory Biomarker Laboratory at Mount Sinai that is actively seeking validated biomarkers for ocular surface disease. Dr. Asbell has authored and co-authored hundreds of articles and book chapters and presented over 200 lectures and courses. Dr. Asbell served on the board of directors of the Tear Film and Ocular Surface Society, the Cornea Society, the Eye Bank for Sight Restoration and Program Committee-Cornea for ARVO. She is currently the Deputy Editor of Eyewiki, which is sponsored by the American Academy of Ophthalmology, Editor in Chief of ECL, the official journal of CLAO, and Section Editor of Cornea for BMC.

Dr. Joseph Tauber, MD. Dr. Tauber joined our Scientific Advisory Board in March 2018. He has been a principal investigator in over 125 research studies of high-risk corneal transplantation, inflammation and allergic eye diseases, corneal infectious diseases and numerous studies related to DES. Dr. Tauber has written five book chapters and over 60 articles in ophthalmology medical journals. He has been awarded the Heed Ophthalmic Foundation Fellowship Award and the National Eye Institute Individual NRSA Award. Dr. Tauber received his doctorate from Harvard Medical School, his training in internal medicine at Beth Israel Hospital and in ophthalmology at Tufts-New England Medical Center. He has served as Clinical Professor of Ophthalmology at Kansas University School of Medicine and University of Missouri-Kansas City School of Medicine. Dr. Tauber specializes in anterior segment surgery, corneal transplantation, the treatment of corneal and external diseases and laser vision correction procedures. A board-certified ophthalmologist, Dr. Tauber is the Founder of Tauber Eye Center in Kansas City, Missouri.

Janos Nemeth, MD. Dr. Nemeth joined the Wize Israel Scientific Advisory Board in October 2015 and has been a member of our Scientific Advisory Board since the closing of the Merger on November 16, 2017. He has performed clinical trials with LO2A in the treatment of CCH and Sjögren’s demonstrating efficacy in these indications. He has been a principal investigator or co-investigator in 25 ophthalmology clinical trials, most of them in Phase III. Dr. Nemeth has written and/or edited 10 books, authored 37 book chapters, and authored 351 scientific articles. He has received numerous awards including the Chibret Award, the Dr. Ferenc Papolczy Foundation First Prize, both in Hungary, as well as the Imre-Blaskovics Prize and the Schulek Vilmos Prize of the Hungarian Ophthalmological Society and the Gábor Brooser Prize of the Hungarian Ophthalmological and Diabetes Societies. Dr. Nemeth is an ophthalmologic surgeon and Board Member of the Drug Discovery and Safety Center at Semmelweis University, Budapest, Hungary. Dr. Nemeth received his doctorate of medicine from the University of Szeged, Hungary. He was a professor of ophthalmology at the University of Szeged, Semmelweis University and at Pazmany Peter Catholic University in Hungary. Dr. Nemeth’s research fields of interest include numerous ophthalmic indications, including Sjögren’s and tear film dynamics.

HISTORICAL STOCK PRICE



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